

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

United States Endoscopy Group, Inc.
Also trading as US Endoscopy
5976 Heisley Road
Mentor
Ohio
44060
USA

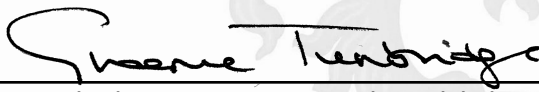
Holds Certificate Number:

FM 75888

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2003-04-18

Latest Revision Date: 2024-08-13

Effective Date: 2024-12-22

Expiry Date: 2027-12-21

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Certificate No: FM 75888

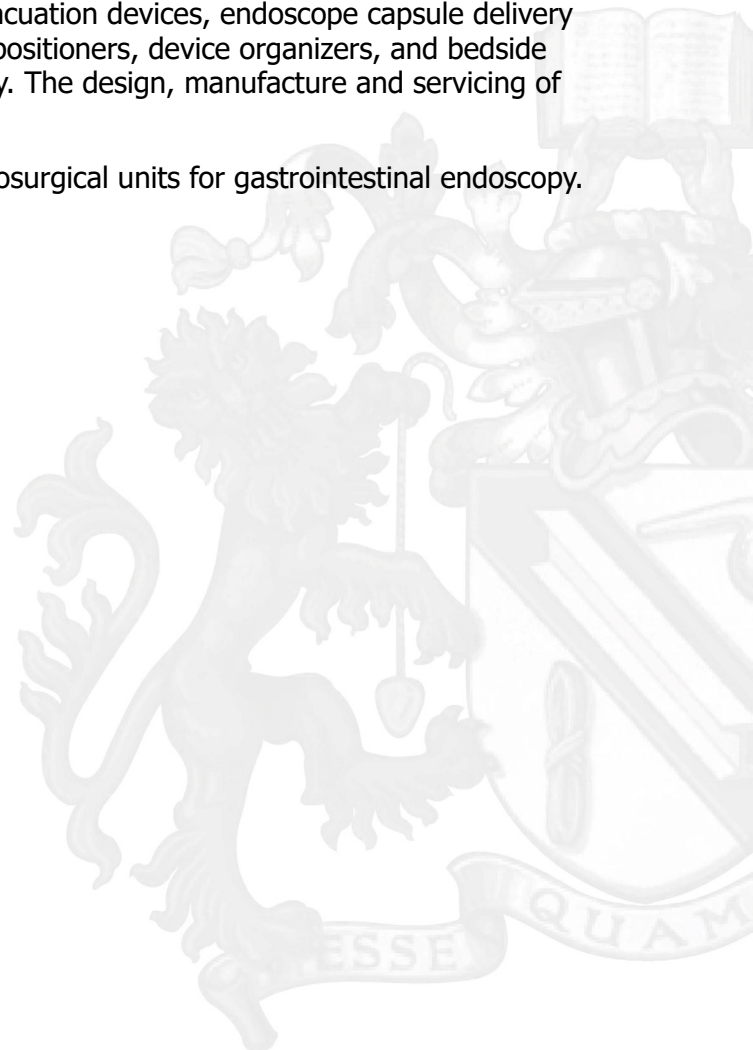
Registered Scope:

The design and manufacture of sterile biopsy forceps, injection needles, clips, tissue sampling devices, grasping devices, endoscope valves, endoscope attachment caps, electrosurgical and non-electrosurgical snares, cryosurgical catheters, and cryosurgical suction tubes for gastrointestinal endoscopy.

The design and manufacture of sterile and non-sterile retrieval devices, EUS balloons, biopsy valves and endoscope tip protectors for gastrointestinal endoscopy.

The design and manufacture of non-sterile overtubes, evacuation devices, endoscope capsule delivery devices, bite blocks, polyp traps, cleaning brushes, head positioners, device organizers, and bedside endoscope cleaning devices for gastrointestinal endoscopy. The design, manufacture and servicing of powered insufflators for gastrointestinal endoscopy.

The design, manufacture, servicing and installation of cryosurgical units for gastrointestinal endoscopy.



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.
Americas Headquarters: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA

Certificate No: FM 75888

Location

United States Endoscopy Group, Inc.
Also trading as US Endoscopy
5976 Heisley Road
Mentor
Ohio
44060
USA

Registered Activities

The design of sterile biopsy forceps, injection needles, clips, tissue sampling devices, grasping devices, endoscope valves, endoscope attachment caps, electrosurgical and non-electrosurgical snares, cryosurgical catheters and cryosurgical suction tubes. The design of sterile and non-sterile retrieval devices, EUS balloons, biopsy valves and endoscope tip protectors.
The design of non-sterile overtubes, evacuation devices, endoscope capsule delivery devices, bite blocks, polyp traps, cleaning brushes, head positioners, device organizers, bedside endoscope cleaning devices, powered insufflators and cryosurgical units. The manufacture of sterile biopsy forceps, clips, tissue sampling devices, and grasping devices. The manufacture of sterile and non-sterile EUS balloons. The manufacture of non-sterile evacuation devices, endoscope capsule delivery device, endoscope tip protectors, bite blocks, cleaning brushes, head positioners, device organizers, bedside endoscope cleaning devices, and polyp traps.
The manufacture and servicing of powered insufflators. The manufacture, servicing and installation of cryosurgical units for gastrointestinal endoscopy.

United States Endoscopy Group, Inc.
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The manufacture of sterile injection needles, tissue sampling devices, grasping devices, endoscope valves, electrosurgical and non-electrosurgical snares, and endoscope attachment caps.
The manufacture of sterile and non-sterile retrieval devices, biopsy valves, and endoscope tip protectors.
The manufacture of non-sterile overtubes, and cleaning brushes.

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